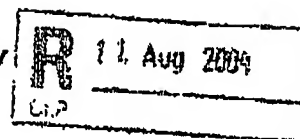


PATENT COOPERATION TREATY



From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

WASCHBUESCH, Klaus
Grenzacherstrasse 124
CH-4070 Basel
SUISSE

PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing
(day/month/year)

09.08.2004

9.11.2004 he
11.9.2004 he
Orientierung US
+ Webpage All II

Applicant's or agent's file reference
Case 21271

REPLY DUE

within 3 month(s)
from the above date of mailing

International application No.
PCT/EP 03/0776

International filing date (day/month/year)
26.09.2003

Priority date (day/month/year)
03.10.2002

International Patent Classification (IPC) or both national classification and IPC
C07D403/A2

Applicant
F. HOFFMANN-LA ROCHE AG

1. This written opinion is the first drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 03.02.2005

Name and mailing address of the International
preliminary examining authority:



European Patent Office
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Authorized Officer

Friebe, F

Formalities officer (incl. extension of time limits)
Hebert, W
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WRITTEN OPINIONInternational application No. **PCT/EP 03/0776****I. Basis of the opinion**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*);

Description, Pages

1-77 as originally filed

Claims, Numbers

1-23 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
 - ☐ the language of publication of the international application (under Rule 43.3(b)).
 - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority in written form.
 - ☐ furnished subsequently to this Authority in computer readable form.
 - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
 - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.
4. The amendments have resulted in the cancellation of:
- ☐ the description, pages:
 - ☐ the claims, Nos.:
 - ☐ the drawings, sheets:
5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

WRITTEN OPINIONInternational application No. **PCT/EP 03/0776**

- ☐ the entire international application,
- ☒ claims Nos. 21,23
because:
- ☒ the said international application, or the said claims Nos. 21 relate to the following subject matter which does not require an international preliminary examination (specify):
see separate sheet
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 23 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the said claims Nos.
2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:
- ☐ the written form has not been furnished or does not comply with the Standard.
- ☐ the computer readable form has not been furnished or does not comply with the Standard.
- V. Reasoned statement under Rule 65.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
1. Statement
- | | | |
|-------------------------------|--------|---------|
| Novelty (N) | Claims | |
| Inventive step (IS) | Claims | 1-20,22 |
| Industrial applicability (IA) | Claims | |
2. Citations and explanations
see separate sheet

**WRITTEN OPINION
SEPARATE SHEET**

International application No. PCT/EP 03/10776

SECTION III

- 1). Claim 21 relates to the treatment of human and/or animal bodies. According to Rule 67(1)(iv) an examination is not required for such a claim.
- 2). Since claim 23 does not contain any technical feature, it is regarded as unclear.

SECTION V

- 3). Relevant prior art is represented by:

D1: WO 02/053534 A (DAIICHI PHARMA.) 11 July 2002 (2002-07-11)

- 4). The claimed matter is novel vis-à-vis D1, since none of the cited examples discloses the specific position of the heteroatom compared to the linking bond between the heterocycle and the core moiety.
The selection over D1 is therefore novel.

- 5). D1 is the closest prior art, since compounds disclosed therein also possess valuable properties for treating diabetes..

Due to the very broad scope disclosed in D1, the current claimed scope is regarded as a selection over D1.

Thus, the problem underlying the current application appears to be the provision of further indole derivatives showing an unexpected effect over D1.

Since the skilled person knows that the compounds embraced by the disclosure of D1 can be used to treat diabetes, the applicant is invited to show that the choice of the specific claimed scope is not arbitrary but based on an unexpected effect.
Since this effect has not yet been shown, an inventive step is not acknowledged.

If the applicant intends to submit comparative data, the comparative example should be the compound 69 on page 315 of D1.

- 6). There is no objection with regard to industrial applicability.

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